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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,870	04/10/2001	Thomas D. Chittenden	104322.147 US5	7819
24395	7590	11/02/2005	EXAMINER	
WILMER CUTLER PICKERING HALE AND DORR LLP			SCHULTZ, JAMES	
THE WILLARD OFFICE BUILDING			ART UNIT	
1455 PENNSYLVANIA AVE, NW			PAPER NUMBER	
WASHINGTON, DC 20004			1635	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/828,870

Applicant(s)

CHITTENDEN ET AL.

Examiner

J. D. Schultz, Ph.D.

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 40-45 is/are allowed.
- 6) ☒ Claim(s) 46-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>28 Sept 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 15 August 2005 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 17 May 2005 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52, 54 and 55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is drawn to a method of identifying an agent capable of modulating apoptosis in a cell, said method comprising assaying an ability of the agent to modulate a heterodimerization activity between a GD domain of a protein or a polypeptide and a Bcl-xl protein or a polypeptide, wherein the heterodimerization activity is defined by an ability

Art Unit: 1635

of the GD domain to interact with the Bcl-xl protein or a polypeptide, and measuring an increase or decrease in heterodimerization activity, thereby identifying said agent capable of modulating apoptosis in the cell, wherein said modulation may be either increasing or decreasing apoptosis.

To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Thus, an applicant complies with the written-description requirement by describing the invention, with all its claimed limitations, and by using such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical, structure/function correlation, methods of making the claimed product, and any combination thereof. The representative sample requirement may be satisfied by supplying structural or functional information, or a combination of both, such that one of skill in the art would be satisfied that applicants were in possession of the genus as claimed. Further, the size of the representative sample required is an inverse function of the unpredictability of the art.

In order to practice the claimed invention, one must first have possession of the genus of GD domain containing proteins or polypeptides. However, the definition provided in the specification does not clearly state what is included by the recitation of the claimed GD domain, or what is excluded. In attempting to determine the extent of such a genus, it appears that the prior art that existed at the time of applicants filing is silent in regards to a definition of exactly

Art Unit: 1635

what constitutes a GD domain containing proteins or polypeptides. The specification teaches that the GD domain is contained within three distinct polypeptides; BIP1A, BAX, and BAK.

Figure 5 teaches that the GD domain consists of a 13 amino acid stretch, of which there appears to be an absolute requirement of 4 specific amino acids at specific locations in set stretch. The position of 5 other amino acids within the stretch appear to have looser structural requirements, meaning that there appears to be some variability at these 5 locations. The remaining 4 amino acids appear to have no homology whatsoever to reach other. The remainder of applicants disclosure regarding what exactly constitutes a GD domain consists of 20 and 28 amino acid containing sequences, all of which possess this 13 amino acid stretch.

In the lack of a very specific definition provided by either of the specification or the prior art, one of skill would be left asking whether the totality of the disclosure provides an implicit definition of what a GD domain containing protein is. It is maintained that the three species (BIP1A, BAX, and BAK) and their truncated variations constitutes an insufficient sample of species that would represent the genus of all GD domain containing proteins. The absolute requirement for the presence of 4 specific amino acids and 5 more variable amino acids within a 13 amino acid stretch is not considered to be a sufficient teaching to allow one of skill to distinguish between a GD domain containing protein as loosely defined in the specification from one that has the 4 specific amino acids but does not have GD domain function. Accordingly, one of skill in the art would be unable to envision additional members of the genus of GD domain containing proteins, and would not consider applicants to be in possession of the claimed invention at the time of filing.

Claim Rejections - 35 USC § 102

Claims 46-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Chittenden et al. (U. S. Patent Number 5,656,725), and is repeated for the same reasons of record as set forth in the action mailed 17 May 2005.

In the action of 17 May 2005, priority of the instant application was granted to U.S. Application Number, 09/236,385, but was denied to U.S. Application Numbers 08/908,795, and 08/440,391. This is because the instant SEQ ID NO: 36 first appears only in 09/236,385. Although SEQ ID NO: 2 of 08/908,597 is a 28mer amino acid sequence which contains embedded within it SEQ ID NO: 36 (a 20mer), priority is denied to this application, because one of skill would not have been led from the longer 28mer of SEQ ID NO: 2 of the parents to the truncated 20mer of the instant SEQ ID NO: 36, because there is no teaching within the specification that SEQ ID NO: 36 is a preferred or contemplated embodiment of SEQ ID NO: 2. The '725 patent thus constitutes prior art, because it published more than one year prior to the accorded filing date of U.S. Application Number 09/236,385, which is January 25, 1999.

Applicants have amended the claims from "comprising" SEQ ID NO: 36 to "consisting essentially of" SEQ ID NO: 36 in an attempt to exclude SEQ ID NO: 2 of the '725 patent, and thus allege that the art does not apply therefore.

This has been fully considered but is not convincing, because applicants have not provided any argument or evidence that the extra amino acids on SEQ ID NO: 2 of the prior art would materially change the characteristics of SEQ ID NO: 36. Furthermore, the specification does not indicate what the basic and novel characteristics of SEQ ID NO: 36 actually are, and

Art Unit: 1635

thus the transitional phrase “consisting essentially of” continues to be interpreted as “comprising.

Support for this reasoning is drawn from M.P.E.P. § 2111.03 [R-2] (with relevant portions bolded):

“The transitional phrase ‘consisting essentially of’ limits the scope of a claim to the specified materials or steps ‘and those that do not materially affect the basic and novel characteristic(s)’ of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original) (Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid “consisting essentially of” certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants’ specification indicated the claimed composition can contain any well-known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). “A consisting essentially of” claim occupies a middle ground between closed claims that are written in a consisting of format and fully open claims that are drafted in a comprising’ format.” PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also Atlas Powder v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama-Rao, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); Water Technologies Corp. vs. Calco, Ltd., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). **For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.”** See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 (“PPG could have defined the scope of the phrase consisting essentially of” for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention.”). See also > AK Steel Corp. v. Sollac, 344 F.3d 1234, 1240-41, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003) (Applicant’s statement in the specification that “silicon contents in the coating metal should not exceed about 0.5% by weight” along with a discussion of the deleterious effects of silicon provided basis to conclude that silicon in excess of 0.5% by weight would materially alter the basic and novel properties of the invention. Thus, “consisting essentially of” as recited in the preamble was interpreted to permit no more than 0.5% by weight of silicon in the aluminum coating.);< In re Janakirama-Rao, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). **If applicant contends that additional steps or materials in the prior art are excluded by the recitation of “consisting essentially of,” applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant’s invention.** In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) (“Although consisting essentially of” is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant’s burden to establish that a step practiced in a prior art method is excluded from his claims by consisting essentially of language.”). (Emphasis supplied).

Since there is no apparent “clear indication in the specification or claims of what the basic and novel characteristics actually are” of the instantly claimed SEQ ID NO: 36, or in SEQ ID NO: 2

Art Unit: 1635

of the prior art, nor have applicants argued or pointed to such an indication, it is applicants burden to show that the extra components of SEQ ID NO: 2 of the prior art would materially change the characteristics of the instantly claimed SEQ ID NO: 36. This burden has not been met by the mere assertion that the amendment causes the prior art to no longer be anticipatory, and the rejection is therefore maintained.

Allowable Subject Matter

Claims 40-45, are allowed, because the amino acid sequence consisting of SEQ ID NO: 36 is considered to be free of the art.

Conclusion

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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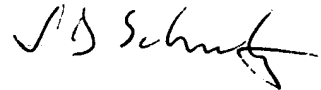
Art Unit: 1635

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JDS

J.D. SCHULTZ, Ph.D.
PATENT EXAMINER

A handwritten signature in black ink, appearing to read "J.D. Schultz", with a stylized flourish at the end.